REMARKS

Applicants delete claims 1-9. Applicants add new claims 10-20. Claims 10-20 are directed to a process for making the excipients only.

Applicants filed an amendment under 37 CFR 1.116 on May 16, 2003.

The examiner issued an advisory action dated June 9, 2003. The examiner stated that: the claims as presented do not overcome the prior art, specifically the Bar-Shaolom reference; the claims appear to be drawn to an intermediate component of a larger pharmaceutical formulation, and do not distinguish from the art; the claims recite that the composition is "free flowing," yet it is unclear how the excipient would flow freely in a complete solid pharmaceutical formulation; also the newly added product-by-process limitations do not impart patentability since the claims are drawn to compositions, and not processes of making said compositions; the end result is the same regardless of how the composition is made.

Applicants do not believe it is unclear how the composition could be "free-flowing" in a solid dosage form. This is because the claimed invention is not directed to a finished dosage form but to a process for making an excipient which can be used later to make a dosage form. The excipient can be free-flowing before being used to make a dosage form.

Applicants also believe the presently amended claims overcome Bar-Shalom because Bar-Shalom is not directed to a process for making an excipient but to eh manufacture of a specific tube-shaped device wherein a molten mixture is extruded into

the pre-formed tube. Bar-Shalom does not disclose nor suggest the manufacture of a free-flowing powderous excipient. The prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP § 2143.

For the reasons expressed above, it is urged that the prior art references cited by the examiner either singly or in combination fail to anticipate or suggest the present invention as defined by the amended claims. Accordingly, a *prima facie* case of obviousness has not been established by the examiner, and the rejection under 35 USC § 103 should be withdrawn.

Please charge any shortage in fees due in connection with the filing of this paper, including Extension of Time fees to Deposit Account No. 11-0345. Please credit any excess fees to such account.

Respectfully submitted,

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COMPLETE LISTING OF ALL CLAIMS IN THE APPLICATION

1-9 (canceled).

10. (new) A process for producing the excipient adapted for use in a solid pharmaceutical dosage form, wherein said excipient is in the form of a free-flowing powder and consists essentially of a pharmaceutically acceptable polymer and from 10 to 50% by weight, based on the total weight of said excipient, of a liquid or semisolid solubilizing surface-active substance; which comprises either spray-drying a solution comprising the surface-active substance and the pharmaceutically acceptable polymer, or processing the polymer and the surface-active substance in an extruder to obtain a homogeneous melt and subsequently converting the melt into the free-flowing powder.

11. (new) The process according to claim 10, wherein the excipient comprises a surface-active substance which has a drop point in the range from 20 to 40°C.

12. (new) The process according to claim 10, wherein the excipient comprises a surface-active substance which has an HLB of from 10 to 15.

13. (new) The process according to claim 10, wherein the polymer in the excipient is a homo- or copolymer of N-vinylpyrrolidone.

14. (new) The process according to claim 10, wherein the excipient comprises from 15 to 40% by weight of the surface-active substance.

15. (new) The process according to claim 10, wherein the excipient comprises ethoxylated sorbitan fatty acid esters as surface-active substances.

16. (new) The process according to claim 10, wherein the excipient comprises the products of the reaction of ethylene oxide with castor oil, hydrogenated castor oil or with 12-hydroxystearic acid as surface active substance.

17. (new) The process according to claim 10, wherein the excipient comprises from 20 to 30% by weight of the surface-active substances.

18. (new) The process according to claim 10, wherein the excipient is in the form of a free-flowing powder of particles having a particle size of from 10 to 1000 µ.

19. (new) The process according to claim 10, wherein the excipient consists of the polymer and the surface-active substance and optionally one or more ingredients selected from the group consisting of flow regulators, dyes, mold release agents, fats, waxes, disintegrants, bulking agents and other conventional tableting excipients.

20. (new) The process according to claim 10, wherein the surface-active substance of the excipient is a non-ionic compound.